



May 20, 2021

Possis Medical, Inc.
Mike Burnside
9055 Evergreen Blvd., N.w.
Minneapolis, Minnesota 55433-8003

Re: K081989

Trade/Device Name: Fetch Aspiration Catheter
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy catheter
Regulatory Class: Class II
Product Code: QEZ

Dear Mike Burnside:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated September 26, 2008. Specifically, FDA is updating this SE Letter as an administrative correction because FDA has created a new product code to better categorize your device technology.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Gregory O'Connell, OHT2: Office of Cardiovascular Devices, (301) 796-6075, Gregory.OConnell@FDA.HHS.gov.

Sincerely,


Gregory W. O'Connell -S
Digitally signed by
Gregory W. O'Connell -S
Date: 2021.05.20
10:13:46 -04'00'

Gregory O'Connell
Assistant Director
Plaque Modification Devices Team
DHT2C: Division of Coronary
and Peripheral Intervention Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

SEP 26 2008

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Possis Medical Inc.
c/o Mr. Mike Burnside
Regulatory Affairs Manager
9055 Evergreen Boulevard N.W.
Minneapolis, MN 55433-8003

Re: K081989

Trade/Device Name: Fetch® Aspiration Catheter
Regulation Number: 21 CFR 870.5150
Regulation Name: Catheter, Embolectomy
Regulatory Class: Class II
Product Code: DXE
Dated: August 29, 2008
Received: September 2, 2008

Dear Mr. Burnside:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality

Page 2 – Mr. Mike Burnside

systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

Bram D. Zuckerman



Bram D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): K 081989

Device Name: The Fetch® Aspiration Catheter

Indications for Use:

The Fetch Aspiration Catheter is indicated for the removal of fresh, soft emboli and thrombi from vessels in the arterial system and coronary vasculature.

Prescription Use X _____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Suzanne R. Valentine
(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K081989

SEP 26 2008

Section 5 – 510k Summary Information

Applicant: Possis Medical, Inc.
 9055 Evergreen Boulevard N.W.
 Minneapolis, MN 55433-8003
 Tel: (612) 780-4555
 Fax: (612) 780-2227 ERN: 2183460

Contact Person: Mike Burnside
 Regulatory Affairs Manager
 Phone: (763) 780-4555
 Fax: (763) 780-2227
 Email: mike.burnside@possis.com

Date Prepared: July 11, 2008

Trade Name: Fetch® Aspiration Catheter

Common Name of Device/ Classification and Code: Catheter,Embolectomy
 Product Code: DXE
 Class II/21 CFR 870.5150 Cardiovascular

Predicate Device: The Fetch Aspiration Catheter - K062172 and K070363
 Possis Medical, Inc.
 9055 Evergreen Boulevard N.W.
 Minneapolis, MN 55433-8003

Device Description: The FETCH Aspiration Catheter is a rapid exchange, low-profile tip, dual lumen catheter that uses a 0.014" (0.36 mm) guide wire to track to the target site. It is used for aspiration of fresh, soft emboli and thrombi. Its outer diameter 0.052" (1.33 mm) or 4F allows advancement to the target site through a 6F (0.070" I.D.) guiding catheter. A radiopaque marker is located about 2 mm from the distal tip. FETCH is provided with an extension line, 30 cc syringe, one-way stopcock and a 40 micron collection basket. This basket can be used to filter aspirated blood for laboratory analysis of collected thrombus.

Intended Use: The Fetch® Aspiration Catheter is indicated for the removal of fresh, soft emboli and thrombi from vessels in the arterial system and coronary vasculature.

Summary of Technological Characteristics: Representative samples of the device underwent testing including but not limited to mechanical testing, biocompatibility testing, and sterility assessment.

Conclusion: Possis Medical, Inc. considers the Fetch Aspiration Catheter to be substantially equivalent to the predicate device listed above. This conclusion is based upon the devices' similarities in functional design, materials, indications for use, and principles of operation.